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A Randomised Controlled Trial of Cognitive Behaviour Therapy or a waiting list for treating
a Specific Phobia of Vomiting (emetophobia)

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Abstract

This is the first randomised controlled trial to evaluate a protocol for cognitive behaviour therapy (CBT) for a Specific Phobia of Vomiting (SPOV) compared with a wait list and to use assessment scales that are specific for a SPOV. Method: 24 participants (23 women and 1 man) were randomly allocated to either 12 sessions of CBT or a wait list.

Results: At the end of the treatment, CBT was significantly more efficacious than the wait list with a large effect size (Cohen's $d = 1.53$) on the Specific Phobia of Vomiting Inventory between the two groups after 12 sessions. Six (50%) of the participants receiving CBT achieved clinically significant change compared to 2 (16%) participants in the wait list group. Eight (58.3%) participants receiving CBT achieved reliable improvement compared to 2 (16%) participants in the wait list group. *Conclusions:* A SPOV is a condition treatable by CBT but further developments are required to increase efficacy.

Key words: emetophobia; specific phobia; vomiting; cognitive behaviour therapy; exposure; randomised controlled trial.

A Randomised Controlled Trial of Cognitive Behaviour Therapy or wait list for a Specific Phobia of Vomiting

A specific phobia of vomiting (SPOV) (also known as “emetophobia”) is a neglected area of research. Its inclusion with Specific Phobia ‘Other type’ in the DSM may partly account for this (Boschen, 2007). A SPOV occurs predominantly in women and commonly develops in childhood with an average duration of 25 years before treatment (Lipsitz, Fyer, Paterniti, & Klein, 2001; Veale & Lambrou, 2006). Epidemiological studies suggest that the prevalence of specific phobias in general is extremely common with a 12-month prevalence of about 7–13% (Becker et al., 2007; Boyd et al., 1990; Kessler, Chiu, Demler, & Walters, 2005; Stinson et al., 2007). Of these, only one study specifically enquired about a specific phobia of vomiting, which had a prevalence of 0.1% (Becker et al., 2007).

Although a SPOV therefore appears relatively uncommon in the community compared with specific phobias in general (Becker et al., 2007), its prevalence may have been deflated in this study by misdiagnosis or comorbidity being given precedent (Boschen, 2007; Manassis & Kalman, 1990; Veale, 2009). For example, obsessive-compulsive symptoms may be observed in the compulsive washing or superstitious behaviours in SPOV that are performed in order to prevent vomiting (Veale, Hennig, & Gledhill, 2015). Hypochondriacal disorder may be misdiagnosed from the significant degree of worrying, reassurance seeking and checking behaviour about possible infections or food poisoning that could cause a person to vomit. Anorexia nervosa may be misdiagnosed when a person is underweight and restricting food to reduce the risk of vomiting. The person may have no disturbance in body image or in their self-evaluation, and may have no fear of gaining weight or becoming fat (Manassis & Kalman, 1990).

A SPOV therefore appears to be rare in the community from one study but this finding is partly at odds with a study that found that 8.8% of the community report a “fear of vomiting” (van Hout & Bouman, 2012). Clinicians report it is one of the more common specific phobias for treatment seeking. This could be because people with a SPOV are often significantly handicapped by the degree of their avoidance behaviour compared with other specific phobias (e.g. they may avoid a desired pregnancy, have a termination of pregnancy or avoid a surgical procedure (Veale & Lambrou, 2006). Lastly, the avoidance of certain types of food and disordered eating may cause the individual to become significantly underweight (Veale, Costa, Murphy, & Ellison, 2012)(Manassis & Kalman, 1990). A SPOV may manifest itself in three main ways: a fear of vomiting themselves, a fear of others vomiting (which may then lead to contagion and vomiting themselves) and a fear of vomiting in front of others and being evaluated negatively (Lipsitz et al., 2001; van Hout & Bouman, 2012).

To our knowledge, there has been no randomised controlled trial for treating a SPOV. A meta-analysis of randomised controlled trials that treated specific phobias in general found *in-vivo* exposure to have the most evidence (Wolitzky-Taylor, Horowitz, Powers, & Telch, 2008). However, this review did not include any trials with a SPOV. It is not known whether a SPOV responds to exposure as well as other specific phobias or whether a protocol should include repeated exposure to actual vomiting. In addition, a generic protocol for exposure may at least need to be modified to include the repetitive (or “compulsive”) behaviours that can occur in emetophobia or to update early aversive memories of vomiting (Veale, Murphy et al, 2013). Most case reports in adults or children with SPOV treated by various forms of cognitive behaviour therapy that included exposure. There are potential practical problems with repeated exposure to oneself vomiting, and so most of the case reports have included various forms of graded exposure to cues of vomiting (Lesage & Lamontagne, 1985; Maack,

Deacon, & Zhao, 2013; McFadyen & Wyness, 1983). This has been supplemented by exposure to a video of others vomiting (Phillips, 1985), adding exposure to interoceptive cues (e.g. creating sensation of nausea) (Hunter & Antony, 2009), adding cognitive therapy and behavioural experiments that included exposure (Kobori, 2011), delivering CBT with exposure in a group format (Ahlen, Edberg, Di Schiena, & Bergström, 2015), adding cognitive restructuring and parent training to exposure (Graziano, Callueng, & Geffken, 2010), adding a feeding program to exposure (Williams, Field, Riegel, & Paul, 2011), adding fluoxetine and clobazepam to exposure (Faye, Gawande, Tadke, Kirpekar, & Bhawe, 2013), adding hypnotherapy to exposure (Wijesinghe, 1974) and lastly adding systemic behaviour therapy to exposure (O'Connor, 1983). Four case reports are described without exposure – one of imaginal coping (Moran & O'Brien, 2005), one of psychotherapy (Manassis & Kalman, 1990) and two reports of hypnotherapy including a form of imagery rescripting (McKenzie, 1994; Ritow, 1979). None of these single cases had an experimental design, and there is likely to be a publication bias of successful cases. Four of those reports involved atypical cases; for example, two of the reports were concerned predominantly with fear of others vomiting (McFadyen & Wyness, 1983; McKenzie, 1994) and two were of atypical social phobia or a preoccupation with nausea (Lesage & Lamontagne, 1985; McNally, 1997). None described a clear theoretical model of SPOV and only one recent study used a validated measure of a SPOV (Ahlen et al., 2015).

Boschen (2007) first developed a model of a SPOV in which he suggested that people with SPOV may be more vulnerable to expressing anxiety through gastrointestinal somatic symptoms such as nausea and “butterflies”, and these were misinterpreted as evidence of imminent vomiting. Veale (2009) emphasised the role of emotional conditioning in which vomiting has become associated with fear and disgust. Past aversive experiences of vomiting (and their cues) become fused with the present often through imagery (Price, Veale, &

Brewin, 2012; Veale, Murphy, Ellison, Kanakam, & Costa, 2013) so that the memories are re-experienced as if they are about to be repeated. Once the association is learned, the core catastrophic appraisal is of nausea as impending vomit and loss of control and the evaluation of vomiting as one of extreme awfulness leading to further anxiety and disgust. There are various responses that then maintain the fear including: (a) experiential avoidance of thoughts and images of the self or others vomiting and interoceptive cues for nausea, (b) avoidance of external cues that could lead to vomiting; (c) hyper-vigilance for monitoring external threats; (d) self-focussed attention and hyper-vigilance for nausea and other gastro-intestinal sensations; (e) worry, self-reassurance and mental planning of escape routes from others vomiting; (f) magical thinking and neutralizing to stop oneself from vomiting; (g) safety-seeking behaviours, including compulsive checking and reassurance seeking (Veale, Hennig, et al., 2015).

A treatment protocol of CBT (Veale, 2009) based on this model includes psycho-education, a formulation of cognitive processes and behaviours maintaining the fear, imagery re-scripting of past aversive experiences of vomiting (Holmes, Arntz, & Smucker, 2007; Veale, Page, Woodward, & Salkovskis, 2015), exposure *in vivo* to cues of vomiting, exposure in imagination and role-plays of vomiting, as well as the dropping of safety-seeking and compulsive behaviours. This model and protocol has not been previously evaluated. Our aim in this RCT was to determine if CBT with this protocol is more clinically effective than a wait list with specific outcome measures for SPOV.

Method

The results are reported according to the CONSORT checklist.

Trial design

A randomised controlled trial in which participants were allocated to either cognitive behaviour therapy or a wait list in equal ratio. There were no changes to the design after the trial commenced.

Participants

The eligibility criterion for participation was the diagnosis of SPOV, using the Structured Clinical Interview for DSM-IV (First, Spitzer, Gibbon, & Williams, 1995). Additional inclusion criteria were as follows: (a) the diagnosis of SPOV must be regarded by the clinician and participant as their principle diagnosis, (b) aged 18 or above; (c) on stable psychotropic medication for 12 weeks prior to randomisation (if relevant); (d) no plans to commence or increase the dose of any psychotropic medication; (e) willingness/ability to travel to the clinic weekly; and (f) a total score of at least 15 on the Specific Phobia of Vomiting Inventory (Veale, Ellison, et al., 2013). Exclusion criteria were as follows: (a) those with an exclusive fear of others vomiting (not of self) as this is atypical; (b) those with a diagnosis of schizophrenia or other psychotic disorder, alcohol or substance dependence, domestic violence, other violent or self-destructive behaviours, or other issue that required treatment in its own right or may interfere in the delivery of therapy; (c) those with suicidal or homicidal intent; (d) those whose English was not sufficiently fluent for CBT; (e) those currently receiving another form of psychotherapy; (f) those who had received CBT for SPOV within the past 6 months.

Participants were provided with a rationale and description of the treatment during the initial phone screening and intake session with the principal investigator. The setting for the study was outpatient private-practice office locations in San Diego County, which included one in La Mesa ($n = 4$), one in Carlsbad ($n = 4$), and one in Escondido ($n = 4$) for the CBT group. All three therapists were doctoral level and licensed. One therapist had minimal experience with emetophobia and exposure therapy. The other two had no experience with

emetophobia. All three therapists were experienced in CBT. Only one therapist participated at each practice site. The principal researcher provided detailed instructions both face to face and in written form; and supervised the therapists via audio recording. The principal investigator was available 24/7 to provide support or answer questions. The treatment was provided at no charge. The study was approved by the Institutional Review Board of Argosy University Southern California.

Interventions

Treatment used a CBT protocol of 12 sessions of approximately 60 minutes duration. The therapists were supervised in the delivery of the therapy throughout the study. Phase 1 (sessions 1-3) of treatment included assessment by the clinician and an agreed-upon formulation of the maintenance of fear. Goal-setting emphasized an improved quality of life and commitment to the values of each participant. Psycho-education about vomiting as normal and adaptive was provided along with information about the experience of anxiety and disgust as they relate to a SPOV. It included an assessment of safety seeking and avoidance behaviors in maintaining symptoms. The importance of practice between sessions was emphasised with the dropping of safety seeking behaviours as a first step.

Phase 2 (session 3-5) of treatment addressed the presence of flash-forwards and flashbacks related to traumatic memories of self or others vomiting. Flash-forwards were addressed using imaginal exposure. Flashback memories were addressed with a trauma model using imagery rescripting.

Phase 3 (sessions 4-7) focussed on dropping the safety-seeking behaviors and cognitive processes contributing to fear. These include an overinflated belief in the ability to control vomiting or events that might lead to vomiting, the need for certainty and control over thoughts and feelings about vomiting, attentional biases and meta-cognitions about worry that have the unintended consequences of increasing anxiety. Exploring and testing beliefs about

gastrointestinal sensations and any related misappraisal addressed the cognitive processes contributing to fear. Arousal-management skills were taught by decreasing self-focussed attention to nausea or other somatic sensations and mindful acceptance of the internal experience. The unintended consequences of safety-seeking behaviours such as mental planning, self-reassurance, and vigilance were highlighted in the way they increase preoccupation, distress and interference in life.

Phase 4 (sessions 6-12) of treatment included a presentation of the rationale for graded exposure to both internal and external cues for vomiting. A hierarchy of feared situations or activities (including avoided foods) was created. Homework and in-session intervention included exposure in vivo to items on the hierarchy and other cues of vomiting, such as pictures, sounds or smells of vomit, exposure in imagination of vomiting and role-playing of past experiences of vomiting. Interoceptive exposure (i.e. eating until full, spinning, reading in the car) was used if appropriate. Exposure to the participant actually vomiting was not used. This was because (a) clinical experience suggests that when people with a SPOV have had exposure to self-induced vomiting, they have reported that it made them even more determined never to vomit, (b) there are no single case experimental designs with long term outcomes described for exposure to actual vomiting that can guide a clinician. Although a behavioural experiment of one episode of vomiting might theoretically assist in altering expectations (especially in someone who cannot recall vomiting in their life), vomiting is difficult to repeat for increasing tolerance. Repeated self-induced vomiting may also be associated with electrolyte imbalance or damage to the dental enamel.

Finally, psychoeducation on relapse prevention (sessions 12) was provided so participants understood that gains are maintained through regular exposure to feared situations.

Outcomes

Outcome measures were administered at assessment, at mid-treatment, at end of treatment, and at follow up. Post-treatment measures were collected after the end of the 12th session or after 12 weeks on the wait list. The follow-up measures were collected between 1.5 and 2 months after the end of treatment and usually returned via the postal system. The primary outcome measure was the Specific Phobia of Vomiting Inventory (SPOVI) (Veale, Ellison, et al., 2013). This is a self-report measure that consists of 14 items rated for frequency ranging from 0 (not at all) to 4 (all the time). The total score ranges from 0 to 56. The scale has a two-factor structure, with one factor of 7 items characterized by avoidance (e.g. “I have been trying to avoid or control any thoughts or images about vomiting”) and a second factor of 7 items comprised of threat monitoring (e.g. “I have been focused on whether I feel ill and could vomit rather than on my surroundings”). Cronbach’s α was .91. The secondary outcome measures were:

1) Emetophobia Questionnaire (EmetQ) (Boschen, Veale, Ellison, & Reddell, 2013). The EmetQ is a 13-item scale and the range is 13-65. The EmetQ has 3 factors. Factor 1 had 6 items focused on avoidance of travel, movement, or locations. Factor II was comprised of 3 items, which centered on themes of dangerousness of exposure to vomit stimuli. Factor III consisted of 4 items that were focused on avoidance of others who may vomit. Cronbach’s α was 0.82.

2) Health Anxiety Inventory (HAI) (Salkovskis, Rimes, Warwick, & Clark, 2002). The HAI is an 18-item self-rated measure of health anxiety. The range for the total is 0-42. Cronbach’s α was .95. The HAI was included because people with SPOV often score highly on this scale (Veale, Ellison et al, 2013).

3) The Anxiety Sensitivity Inventory (ASI) (Reiss, Peterson, Gursky, & McNally, 1986; Vujanovic, Arrindell, Bernstein, Norton, & Zvolensky, 2007). The ASI is a 16-item

scale that measures sensitivity to anxiety symptoms. The range of the total score is from 0 to 64 and Cronbach's α was 0.83.

4) Patient Health Questionnaire (PHQ-9) (Kroenke, Spitzer, & Williams, 2001). The PHQ-9 is a 9-item measure of depressive symptoms, based on DSM-IV. The total score ranges from 0 to 27 and Cronbach's α was .86. A measure of depression was included as there is often comorbidity or depressive symptoms.

5) The Sheehan Disability Scale (SDS) (Sheehan, Harnett-Sheehan, & Raj, 1996). This is a 5-item scale that measures degree of impairment and has a range of 0 (unimpaired) to 30 (highly impaired). Cronbach's α was 0.89.

Sample Size

The sample size was calculated on the following assumptions from routine audit. If the SPOVI score is 16 after CBT and 35 on the wait list with a pooled standard deviation of 15 and alpha (type 1 error) of 0.05 and power of 0.80, then the sample size required is 10 per group. Assuming two drop-outs per group, this would require 12 per group to be recruited or a total of 24. There was no clustering by care providers.

Randomisation

Participants were randomly assigned to either the treatment condition or the control condition, by the use of a predetermined randomised sequence list created by Microsoft Office Excel 2007. The participants assigned to the CBT group were assigned to a clinician based on location and convenience of travel.

The random allocation sequence was concealed in a locked file until interventions were assigned.

The principal investigator generated the allocation sequence, enrolled participants, and assigned participants to their groups after randomisation.

Blinding. Participants or those administering the interventions were not blinded to group assignment.

Statistical Methods

Factorial ANOVA was used to determine change for emetophobic symptoms and other general measures across time. Repeated measures ANOVA was used in which time was measured at 3 points across 2 groups. The effect size was calculated using Cohen's d and Eta Squared (η^2). Using Cohen's d , > 0.8 is regarded as a strong effect size, while > 0.5 and 0.2 are moderate and weak effect sizes respectively. Using η^2 , a strong effect size is > 0.14 , while moderate and weak effect sizes are > 0.06 and 0.01 respectively. The numbers in each group who achieved reliable and clinically significant change was determined on the SPOVI and EmetQ at follow-up (Jacobson & Truax, 1991). We used criterion 'c', which is the greater likelihood of a participant being in the normative distribution than a clinical distribution after treatment. Criterion 'c' for the SPOVI was a cut-off score of 8 calculated from a clinical group (*mean* 30.6, *SD* 12.9) and a community group (*mean* 1.5, *SD* 3.5) and the repeat reliability from a clinical sample ($r = 0.85$) in a previous study (Veale et al., 2012). For the EmetQ, criterion 'c' was a cut-off score of 23 calculated from a clinical group (*mean* 37.25, *SD* 8.91) and a community group (*mean* 10.58, *SD* 7.63) and the repeat reliability from a clinical sample ($r = 0.76$) (Boschen et al., 2013).

Results

Participant flow

Figure 1 is a CONSORT flow diagram of the progress during different phases. There were no protocol deviations from the study as planned.

-----Figure 1 about here-----

Implementation of intervention

Participants in the CBT group took 12 to a maximum of 23 weeks ($n = 1$). The mean was 18 weeks to complete the 12 sessions due to illness, vacations or other events. All participants in the wait list group completed their measures at 12 to 20 weeks with a mean of 13 weeks.

Recruitment

Participants were recruited between May 2013 and June 2014, and followed up between approximately 1.5 and 2 months after completion of treatment.

Baseline data

The baseline demographic and clinical characteristics of each group are provided in Table 1. Three in the CBT group were taking one or more psychotropic medications (clonazepam, alprazolam, 2 on escitalopram, aripiprazole, olanzapine), as were five in the wait list group (lorazepam; bupropion; sertraline; quetiapine; and two on alprazolam). Four in the CBT group had had one or more previous psychological therapies for SPOV (two CBT without exposure and two psychotherapy); six in the wait list group had had previous therapy (four CBT without exposure; four hypnotherapy; three psychotherapy; and one EMDR).

Numbers analysed

Analysis was by “intention-to-treat”. In the CBT group, one participant dropped out and had missing data at the end of treatment and so their mid-treatment data were carried forward. In the wait list group, none had missing data at the end of treatment.

There were two participants in the CBT group with missing data at follow-up. These were excluded as there was a possibility of deterioration or relapse. After the wait list, participants were offered CBT and a further seven were treated and included in a within group analysis. Three declined further treatment after the waiting list and two had medical reasons to prevent treatment at this time.

Outcomes and estimation

The therapist completed a checklist of interventions used after each session. Each treatment session was audiotaped to ensure fidelity to the protocol; over 13% of random session recordings were audited by the first named author. Client value focussed goal-setting, psycho-education, addressing safety behaviours, weekly homework, arousal management, addressing cognitive processes, exposure, and relapse prevention were part of treatment for every group participant. Other strategies included on the checklist were used as needed. There was only one deviation from the protocol in the sessions that were audited. In this case the therapist was immediately retrained in the procedure of Imagery Rescripting before resuming sessions.

The primary outcome measure and estimated effect size on each of the main outcome measures are shown in Table 2. There were no significant differences between groups pre-treatment on any of the measures. Repeated measures ANOVAs were conducted for each of the primary and secondary outcome measures. For the primary outcome, the SPOVI, post-hoc pairwise comparisons found that SPOVI scores were significantly lower in the CBT group than the control group at mid-treatment ($p < .01$) and post-treatment ($p \leq .001$). In addition, *within* the CBT group, SPOVI scores were significantly lower at mid-treatment compared to pre-treatment ($p \leq .001$), and at post-treatment compared to pre-treatment ($p \leq .001$). There was no significant difference in outcomes between the therapists at the three centres.

Analysis is however limited by the small numbers.

A similar pattern of results was seen for EmetQ scores, the significant interaction was between the groups at mid-treatment ($p < .05$) and post-treatment ($p \leq .001$), with the CBT group having lower scores than the wait-list group. Similarly, *within* the CBT group EmetQ scores were significantly lower at mid-treatment compared to pre-treatment ($p \leq .001$), and at post-treatment compared to pre-treatment ($p \leq .001$).

In regards to HAI scores, post-hoc pairwise comparisons revealed that there was no significant difference between wait list and CBT group scores at any time. The HAI scores were significantly lower at post-treatment than mid-treatment in the wait list group ($p < .05$). Within the CBT group, the HAI was significantly lower between post-treatment and pre-treatment ($p \leq .001$) in the CBT group ($p < .01$).

A significant main effect of time but not group was found for ASI scores, and post hoc pairwise comparisons revealed the only significant differences *between* wait list and CBT groups was at post-treatment ($p < .01$). There was no significant difference between any time points for the wait list group. ASI scores were significantly lower within the CBT group at mid-treatment compared to pre-treatment ($p < .01$), at post-treatment compared to mid-treatment ($p < .05$).

For PHQ-9 scores there was a significant effect of time, with post hoc pairwise comparisons showing that the significance was between pre and post-treatment ($p \leq .05$), with post-treatment PHQ-9 scores being significantly lower than pre- and mid-treatment scores. However, there was no effect of group or any interaction.

For the Sheehan Disability Scale, post hoc pairwise comparisons revealed that there was a significant difference *between* SDS scores of wait list and CBT at mid-treatment ($p < .05$) and post-treatment ($p < .05$). There was a significant reduction in SDS scores within the CBT group for pre to post-treatment ($p \leq .001$).

There was a very large effect size ($d = 1.53$) between the groups with a confidence interval of 0.62 - 2.44, for the primary outcome measure between the two groups after 12 sessions (Table 2). Information on secondary outcomes is also presented in Table 2. Table 3 provides the categorical outcomes on reliable and clinically significant change. Here the SPOVI was more sensitive to change than the EmetQ with half of the participants achieving clinically significant change on the SPOVI compared to a quarter on the EmetQ. Eight out of

12 participants made reliable improvement on the SPOVI in CBT compared to two out of 12 in the wait list. Numbers who showed reliable improvement on the SPOV were compared for the CBT and wait list group, with Fisher's exact probability test revealing that significantly more participants in the CBT group achieved reliable improvement compared to those in the wait list group as measured by the SPOV ($p \leq .05$) and the EmetQ ($p \leq .05$).

Participants on the waiting list were offered CBT ($n=7$) at the end of the trial and their outcome data is provided in Supplementary Table 4 and 5. The effect size on the SPOVI in the group receiving CBT after the wait list was similar to that found in the first group ($d = 1.96$) and the proportion of participants who achieved clinically significant change and reliable improvement was also similar to the first group at follow-up.

Adverse events

There were no reported adverse events from treatment.

Discussion

This is the first randomised controlled trial of individual CBT delivered by a therapist for SPOV, which demonstrated that CBT is superior to a waiting list on rating scales, which are specific for a SPOV. There was a large effect size in the main outcome measure, with significantly lower scores by the end of treatment for patients in the CBT group compared to those in the wait list group, and by the end of treatment 50% achieved reliable and significant change. Treatment gains were maintained at follow-up. The most common outcome was of reliable improvement suggesting that nearly 2/3 of participants can expect *as a minimum* a change from a phobia to a fear of vomiting and to be significantly less distressed and more functional in their life. This might be a similar state to the 8.8% of the community who report a fear of vomiting who have mild distress or interference in life but do not have a diagnosis of a SPOV (van Hout & Bouman, 2012). The treatment was acceptable in the CBT group with only one dropout. Change was demonstrated in two specific measures for a SPOV as

well as general measures of psychopathology and disability. The study has highlighted greater sensitivity to change in the SPOVI than the EmetQ. This may be because the SPOVI includes several cognitive processes and safety behaviours, whereas the EmetQ is weighted more towards behavioural avoidance. The frequency of cognitive processes may therefore decrease before behavioural avoidance. There are no RCTs to compare with, although one report of group CBT found a within group effect size on the EmetQ of Cohen's d of 1.18 at 3 months (Ahlen et al., 2015).

The main limitation of the study is the small sample size. Therefore, there was a wide confidence interval in effect size. Further limitations are that there was no clustering by care providers although there were no differences in therapist treatment effect, which would be difficult to obtain with such small numbers. The comparator was a waiting list and it is not therefore possible to determine the degree of therapist non-specific effects. Further research is required to compare CBT against a treatment, which is rated by participants as having equal credibility and expectation for change. Intention to Treat Analysis was justified since missing data occurred only in the CBT group, which may bias the outcome against the treatment group. Outcomes were at 1-2 month follow-up and it is not known whether improvements were maintained in the long term. The outcome was dependent on self-report and there was no blind observer (for example, a behavioural avoidance measure of vomiting or a repeat of the structured clinical interview for a diagnosis of a specific phobia). Two participants made reliable improvement on the SPOVI (of whom one made improvement on the EmetQ) whilst on the wait list. Given the chronic nature of a SPOV, this is unusual. On further enquiry, these two participants were atypical in their presentation. The first participant's symptoms were mainly present before and during travelling, which she did quite often and necessitated some accommodation of her schedule in order to participate in the study (i.e. measures were completed when she was not travelling); the other participant

qualified for the study with a minimum score, had little avoidance, no concerns with food, and few safety behaviours. Her main distress was when her husband was sick and she was also avoiding pregnancy due to her fear. The first went on to complete the treatment component of the study and reported it was still helpful for her. The second participant dropped out before the treatment component. Excluding milder or episodic variations of SPOV may be an important in future RCTs.

Generalizability

Because very little is published on a specific phobia of vomiting, it is not known how representative our sample is. We excluded people who exclusively fear others vomiting rather than their selves vomiting and therefore the results cannot be generalised to this population. The phobia was judged to be the principle diagnosis and there was limited comorbidity. The exclusion criteria were standard for RCTs in CBT and there were no exclusions because of the criteria. To date, this trial is the best available evidence for the treatment of a SPOV by CBT with a RCT. The participants were self-referred and recruited by advertising but there is no evidence that they are different to patients presenting in routine clinics. It should be possible to generalise the treatment protocol to routine clinic patients.

Overall Evidence

Our conclusion is that a SPOV is a treatable condition but not everyone responds. In such cases, the treatment may need to be stepped up to a more intensive programme (e.g. a longer treatment with more therapy assisted exposure similar to stepped care in obsessive compulsive disorder (Veale et al., 2016). Further research is required to improve outcome and to evaluate a time-intensive CBT similar to treating other specific phobias (Davis III, Ollendick, & Öst, 2012).

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Figure 1.
Flowchart for participants

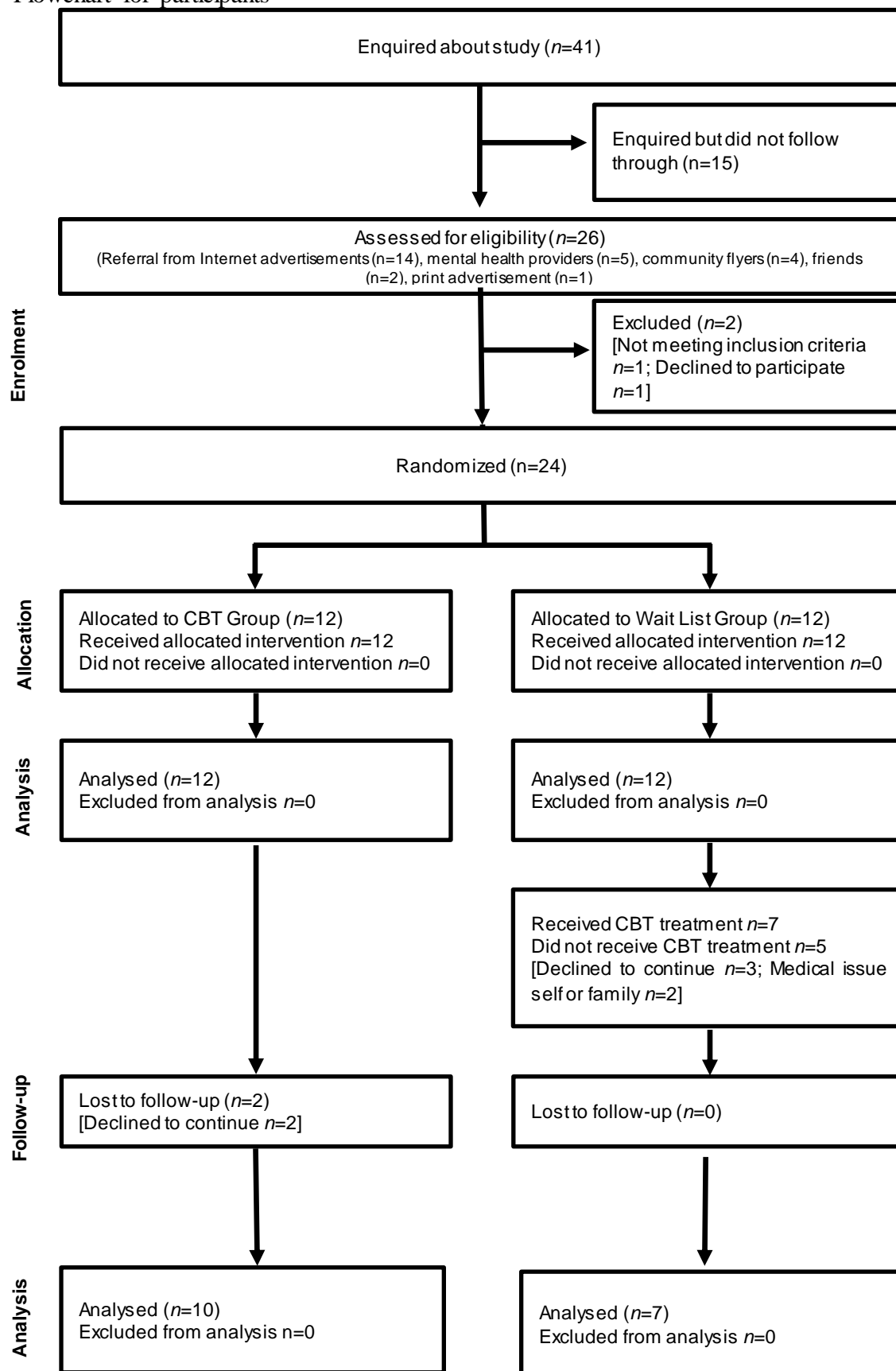


Table 1.
Characteristics of Participants by CBT and Wait List Group

Variable		CBT (<i>n</i> = 12)	Wait List (<i>n</i> = 12)	<i>t</i>	<i>df</i>	<i>p</i>	<i>d</i>
Age in Years, <i>M</i> (<i>SD</i>)		35 (8)	32 (17)	-0.48	22	0.64	0.23
Age at Onset, <i>M</i> (<i>SD</i>)		5 (4)	6 (3)	0.51	22	0.10	0.28
		CBT (<i>n</i> = 12)	Wait List (<i>n</i> = 12)	χ^2	<i>df</i>	<i>p</i>	<i>V</i>
Gender	Male	1	0	1.77	1	0.18	0.38
	Female	11	12				
No. of Children		11	7	1.84	2	0.56	0.20
Marital Status	Married	10	7	2.20	2	0.37	0.21
	Never Married	2	4				
	Widowed	0	1				
Ethnicity	Caucasian	7	9	0.35	1	0.67	0.12
	Hispanic	4	3				
	Unstated	1	0				
Comorbid current Diag.	Depressive Disorder	2	1				
	GAD	0	1				
	OCD	0	1				
	Other phobia	0	1				
	Panic Disorder	1	3				
	With agoraphobia	1	1				
	Social Phobia	1	0				
	Anxiety Disorder NOS	1	0				

Table 2.
Mean, standard deviation, probability and effect sizes within and between groups

Measure	Time	Cognitive Behaviour Therapy (<i>n</i> = 12)		Waiting List (<i>n</i> = 12)		Comparisons of Main Effects and Interactions	Between Group Differences	<i>p</i>
		Mean (<i>SD</i>)	ES (Cohen's <i>d</i>) [95% CI]	Mean (<i>SD</i>)	ES (Cohen's <i>d</i>) [95% CI]	1. Time 2. Intervention 3. Time x Intervention <i>F(df) = F value (^p), ES (<i>n</i>²) [90% CI]</i>		
Specific Phobia of Vomiting Inventory	Pre-	28.75 (12.47)		32.92 (12.07)		1. <i>F</i> (1.38, 30.44) = 11.72 ^c <i>n</i> ² = 0.35 [0.12, 0.51]		
	Mid-	14.33 (10.47)		32.67 (16.79)		2. <i>F</i> (1, 22) = 9.20 ^b <i>n</i> ² = 0.30 [0.09, 0.54]	1.31 [0.43, 2.19]	^b
	Post-	9.50 (9.02) ^b	1.77 [0.83, 2.71]	30.75 (17.44)		3. <i>F</i> (1.38, 30.44) = 8.16 ^b <i>n</i> ² = 0.27 [0.06, 0.44]	1.53 [0.62, 2.44]	^c
	Follow-up	6.20 (6.63) ^b	2.26 [1.23, 3.28]					
Emetophobia Questionnaire	Pre-	48.33 (8.33)		52.67 (6.80)		1. <i>F</i> (2, 44) = 12.46 ^c <i>n</i> ² = 0.36 [0.16, 0.49]		
	Mid-	40.50 (11.62)		50.83 (10.46)		2. <i>F</i> (1, 22) = 7.87 ^b <i>n</i> ² = 0.26 [0.04, 0.46]	1.19 [-0.26, 2.13]	^a
	Post-	35.17 (12.42) _b	1.24 [0.37, 2.12]	51.67 (8.98)		3. <i>F</i> (2, 44) = 8.80 ^c <i>n</i> ² = 0.29 [0.09, 0.42]	1.52 [0.61, 2.43]	^c
	Follow-up	28.90 (11.37) _b	1.95 [0.98, 2.92]					
Health Anxiety Inventory	Pre-	22.50 (11.21)		21.17 (9.06)		1. <i>F</i> (2, 44) = 11.31 ^c <i>n</i> ² = 0.34 [0.14, 0.47]		
	Mid-	18.33 (7.57)		22.25 (10.52)		2. <i>F</i> (1, 22) = 0.33 <i>n</i> ² = 0.02 [0.00, 0.17]		
	Post-	15.00 (6.86) ^a	0.81 [-0.03, 1.64]	18.50 (9.08) ^b	0.38 [-0.43, 1.19]	3. <i>F</i> (2, 44) = 3.54 ^a <i>n</i> ² = 0.14 [0.00, 0.27]		

	Follow-up	15.25 (7.96) ^b	0.75 [-0.08, 1.57]				
Anxiety Sensitivity Index	Pre-	28.42 (13.04)		29.58 (7.56)	1. $F(2, 44) = 7.22$ ^b $n^2 = 0.25$ [0.06, 0.39]		
	Mid-	20.33 (10.47) ^b	0.68 [-0.14, 1.51]	27.25 (11.38)	2. $F(1, 22) = 3.51$ $n^2 = 0.14$ [0.00, 0.35]		
	Post-	15.75 (10.28) ^c	1.08 [0.22, 1.94]	29.42 (11.03)	3. $F(2, 44) = 6.08$ ^b $n^2 = 0.22$ [0.04, 0.36]	1.28 [0.40, 2.16]	^b
	Follow-up	13.25 (9.77) ^c	1.32 [0.43, 2.20]				
Patient Health Questionnaire	Pre-	6.50 (6.33)		5.92 (5.89)	1. $F(2, 44) = 4.87$ ^a $n^2 = 0.18$ [0.02, 0.32]		
	Mid-	5.25 (5.21)		7.92 (5.89)	2. $F(1, 22) = 0.86$ $n^2 = 0.04$ [0.00, 0.22]		
	Post-	2.58 (2.69)		5.67 (3.89)	3. $F(2, 44) = 2.80$ $n^2 = 0.11$ [0.00, 0.24]	0.92 [0.08, 1.77]	^a
	Follow-up	2.92 (2.75)					
Sheehan Disability Scale	Pre-	13.58 (8.23)		11.83 (7.63)	1. $F(1.55, 34.15) = 8.47$ ^b $n^2 = 0.28$ [0.07, 0.44]		
	Mid-	6.33 (7.04) ^b	0.95 [0.10, 1.79]	14.33 (10.17)	2. $F(1, 22) = 2.41$ $n^2 = 0.10$ [0.00, 0.30]		
	Post-	3.83 (6.77) ^c	1.29 [0.41, 2.17]	12.08 (9.37)	3. $F(1.55, 34.15) = 12.21$ ^c $n^2 = 0.36$ [0.13, 0.51]	0.97 [-4.25, 2.30]	^a
	Follow-up	3.92 (6.78) ^c	1.28 [0.40, 2.16]				

ES, Effect size, SD, standard deviation; ^a = $p < 0.05$; ^b = $p < 0.01$; ^c = $p \leq 0.001$, compared to pre-treatment or between groups

		Clinically significant change	Reliable improvement	No reliable change	Reliable deterioration	
Table	CBT ($n = 12$)	SPOVI	6 (50%)	8 (66.7%)	4 (33.3%)	0
		Emet-Q	3 (25%)	6 (50%)	6 (50%)	0
	Wait List ($n = 12$)	SPOVI	2 (16.7%)	2 (16.7%)	10 (83.3%)	0
		Emet-Q	0 (0%)	1 (8.3%)	11 (91.7%)	0
						3.

Numbers who made clinically significant change and reliable improvement in CBT and Wait List Group

Supplementary Table 4.

Numbers who made clinically significant change and reliable improvement at follow-up in those who received CBT after wait list

	Clinically significant change	Reliable improvement	No reliable change	Reliable deterioration
SPOVI (<i>n</i> = 7)	3 (42.8%)	4 (57.1%)	3 (42.8%)	0
EmetQ (<i>n</i> = 7)	1 (14.2%)	6 (85.7%)	1 (12.5%)	0

Supplementary Table 5.

Post-treatment and follow-up of mean, standard deviations and effect sizes for group who received CBT after the wait list (n=7)

Measure	Time	Mean (SD)	<i>p</i>	ES; Cohen's d (95% CI)
ES,	Specific Phobia of Vomiting Inventory	Pre-Treatment		
		Mid-Treatment		1.21 [-4.55, 6.96]
		Post-Treatment	**	1.96 [-3.38, 7.29]
		Follow-up	**	1.95 [-3.32, 7.22]
	Emetophobia Questionnaire	Pre-Treatment		
		Mid-Treatment	**	1.45 [-2.79, 5.70]
		Post-Treatment	***	2.19 [-2.52, 6.89]
		Follow-up	***	1.95 [-3.12, 7.02]
	Health Anxiety Index	Pre-Treatment		
		Mid-Treatment		0.41 [-4.54, 5.36]
		Post-Treatment		0.76 [-3.82, 5.35]
		Follow-up	*	0.64 [-4.25, 5.54]
	Anxiety Sensitivity Index	Pre-Treatment		
		Mid-Treatment	**	1.03 [-5.00, 7.07]
		Post-Treatment	**	1.25 [-4.66, 7.15]
		Follow-up	***	1.69 [-3.81, 7.19]
	Patient Health Questionnaire	Pre-Treatment		
		Mid-Treatment		-0.24 [-4.34, 3.87]
		Post-Treatment		0.22 [-3.17, 3.61]
		Follow-up		0.36 [-3.02, 3.74]
	Sheehan Disability Scale	Pre-Treatment		
		Mid-Treatment		0.34 [-2.99, 3.66]
		Post-Treatment		0.69 [-2.34, 3.73]
		Follow-up	*	1.06 [-1.90, 4.02]

effect size; *SD*, standard deviation; *CI*, confidence interval. * $p < 0.05$; ** $p < 0.01$; *** $p \leq 0.001$, compared to pre-treatment

